

**REMARKS**

Receipt of the Office Action mailed April 25, 2005 is acknowledged. Claim 21 has been amended. Support for the amendment to claim 21 can be found throughout the original disclosure, for example, in the original claims. Claims 23 and 26-29 have canceled without prejudice or disclaimer. Upon entry of the amendment, claims 21, 22, 24 and 25 will be pending in the application. No new matter is believed to be entered.

**35 USC 112, Second Paragraph Rejection**

Claims 21-25 stand rejected under 35 U.S.C. section 112, second paragraph. Reconsideration and withdrawal of the rejections are respectfully requested. Claim 21 has been amended to provide antecedent basis for "said 10% portion." The rejection of claim 23 is moot in view of the cancellation of claim 23.

**35 U.S.C. Section 103 Rejections**

Claim 21 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Cusack et al. (U.S. Patent No. 5,302,348). Reconsideration and withdrawal of the rejection are respectfully requested. The Examiner takes the position that Cusack et al. disclose the claimed invention with the exception of the 10% portion. However, the examiner concludes that it would have been obvious at the time of the invention to modify Cusack et al. to scan the 10% portion closest to the first cavity through routine experimentation.

Applicants respectfully submit that Cusack et al. do not teach or suggest the other claimed features in addition to the 10% portion limitation. For example, the Office Action asserts that "[t]he conduit can comprise a clot specific surface that may be plasma treated or otherwise treated to provide more efficient clotting (column 6, lines 32-40), which examiner interprets as an agglutination reagent." Applicants

respectfully submit that it is not reasonable to interpret the surface of the narrowed portion of the capillary conduit described in Cusack et al. as an agglutinating reagent. The patent describes this in many places as having a rough surface finish, which is a physical attribute rather than a chemical reagent:

- Column 10, Line 44: "*The coagulation is promoted by the roughened surfaces of the test capillary conduit 30 within the narrowed region 44.*"
- Column 6, Line 33: "*Additionally, the surface texture of the test capillary conduit 30 within the narrowed region 44 is roughened.*"
- Column 6, Line 39: "*The textured surface within the narrowed region 44 can be produced either by forming a texture on the surface of the mold used to form the cuvette 12 or texturing the narrowed region 44 after molding with any known etching technique.*"
- Column 11, Line 67: "*one restriction region within said conduit means has a textured surface, whereby said textured surface promotes the coagulation of the blood sample within said at least one restricted region.*"

Cusack et al. at column 6, starting with line 35 discloses "*[t]he narrower area within the conduit is a clot specific surface and may be plasma treated, chemically treated or otherwise treated or roughened to provide a more efficient clotting surface.*" High-energy corona discharge treatments (aka plasma treatments) and chemical treatments are often used to etch or texture the of plastics at a microscopic level. Such treatments cannot reasonably be considered to be a reagent of any type.

Moreover, Cusack et al. fail to teach or suggest "scanning the liquid" with light having "predetermined wavelengths" as set forth in step (c) of Claim 21. The photoelectric sensors which the Examiner relies upon in meeting this claimed feature are actually utilized in Cusack et al. to detect the passing of a fluid front as part of a means to measure fluid flow rate. Once the fluid front has been detected, there is no more meaningful information gathered by the photoelectric sensors (i.e., these are utilized in a binary fashion rather than an analog fashion). This does not constitute "scanning the liquid". Furthermore, Cusack et al teaches that the light

source ".....may be incandescent bulbs, light emitting diodes, or the like." In other words, either device will work fine in this application. However, an incandescent bulb is a continuous, broad spectrum producer of light, and there is no mention of optical bandpass filtration in Cusack et al. Therefore, there is no predetermination of wavelength disclosed or suggested in Cusack et al.

Furthermore, Cusack et al. fail to teach or suggest the reciprocation of fluid between the large diameter and the small diameter portions of the flow channel as claimed. In Cusack et al. the reciprocation of fluid is performed for very different reasons compared to the present application. In the case of Cusack et al., flow of whole blood over the roughened narrow surface of the flow capillary is required to not only grow the clot through continued abrasion of platelets and capture of red blood cells within the fibrin mesh of the clot, but is also a key element of the sensing mechanism of the device (i.e., longer delays between photoelectric sensing events due to continuing narrowing of the restricted portion of the flow channel). In the present application, the reciprocal flow is first utilized to perform mixing of the sample and agglutinating reagent, and then sensing of non-uniformities in the mixture. For instance, in the case of a negative reaction, there is no agglutination, so the mixture is essentially uniform as one scans the mixture volume. For weak or strong reactions, there is an absorbance signature as one scans the mixture volume. For example, strongly agglutinating mixtures will tend to pass a high absorbing "clump" of cells from the larger diameter portion of the flow channel to the narrowed portion of the flow channel late in the flow process due to settling of the mass. The volume of fluid scanned earlier in the flow process will be largely depleted of cells due to the agglutination, and will therefore have a low absorbance signature. Thus, Cusack et al. fail to teach or suggest the claimed invention and reconsideration and withdrawal of the rejection are respectfully requested.

Claims 22 and 23 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Zabetakis et al. (U.S. Patent No. 5,773,305) in view of Cusack et al. (U.S. Patent No. 5,302,348). Reconsideration and withdrawal of the rejection are respectfully

requested. The Examiner takes the position that Zabetakis et al. teach the claimed invention except for scanning of the sample at predetermined wavelength or an agglutinating reagent within the first cavity.

First, applicants submit that claim 22 is patentable over the combination of Cusack et al. and Zabetakis et al. for the reasons set forth above with respect to claim 21. That is, *inter alia*, Cusack et al. fail to teach or suggest an agglutination reagent or making an optical scan of the liquid.

Furthermore, the teaching of Zabetakis is that of providing a means to achieve a homogenous mix of fluids rather than moving fluids in a fashion gentle enough to promote and detect agglutination reactions, many of which can be quite fragile and are easily destroyed by fluid shear forces. Thus there would have been no motivation to combine the teaching of Zabetakis et al. and Cusack et al. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Claims 24 and 25 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Cusack et al. (U.S. Patent No. 5,302,348) in view of Shepherd et al. (WO 94/08237). Reconsideration and withdrawal of the rejection are respectfully requested.

For the same reasons set forth above, claims 24 and 25 are patentable over the combination of Cusack et al. and Shepherd et al. for the reasons set forth above with respect to claim 21. That is, *inter alia*, Cusack et al. fail to teach or suggest an agglutination reagent or making an optical scan of the liquid.

Furthermore, Shepherd et al teaches a method for determination of the various species of hemoglobin. Claims 24 and 25 of the application are directed to the detection of agglutinated cells rather than hemoglobin. Thus, there would have been no motivation to combine the teaching of Shepherd et al. and Cusack et al. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

The examination of these claims and passage to allowance are respectfully requested. An early Notice of Allowance is therefore earnestly solicited. Applicants invite the Examiner to contact the undersigned at (732) 524-1496 to clarify any unresolved issues raised by this response.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Account No. 10-0750/CDS0255/TJB. This sheet is submitted in triplicate.

Respectfully submitted,

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